MAR 3 0 2000

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K000046

RICHARD WOLF
MEDICAL INSTRUMENTS CORPORATION

510(k) Summary of Safety and Effectiveness

Submitter	
Company / Institution name: **Richard Wolf Medical Instruments Corp.**	FDA establishment regulation number: 14 184 79
Division name (if applicable): N.A.	Phone number (include area code): (847) 913-1113
Street address: 353 Corporate Woods Parkway	FAX number (include area code): (847) 913-0924

City:	State/Province:	Country:	ZIP/Postal Code:
Vernon Hills	Illinois	USA	60061

Contact name: Mr. Robert L. Casarsa

Contact title: Quality Assurance Manager

Product Information	
Trade name: Endoscopic Spine System Set	Model number: 8792.xxx, 8793.xxx, and others
Common name: Spinal Arthroscopic Set	**Classification Name:** Arthroscope and Accessories

Information on devices to which substantial equivalence is claimed

510(k) Number	Trade or proprietary or model name	Manufacturer
1 K973405	1 Yeung Endoscopic Spine System	1 Richard Wolf
2	2	2
3	3	3
4	4	4

1.0 Description

The set consists of endoscope, forceps, sheath, obturators, adapters, trephine, punch, scissors, dilators, cannulas, and caps. It is designed to be compatible with other available systems. The design incorporates an increased emphasis on quality imaging. The scope is designed to provide clear visualization of spinal anatomy and pathology through its unique multichannel flow integrated system and working channels.

2.0 Intended Use

The "KESS" instrument set is used to perform endoscopic interventions in the lumbar spine, e.g. decompression of intervertebral discs. The intervention is performed through surgically produced passages.

3.0 Technological Characteristics

The Knight Endoscopic Spine System (KESS) are modified instruments from the Yeung Endoscopic Spine System (YESS), 510(k) K973405.

The KESS endoscopes and instruments are thinner than the YESS devices. The KESS System provides access to the spine under visualization by x-ray; the Yeung System yields accesse to the spine with a positioning probe.

4.0 Substantial Equivalence

The submitted devices pose the same type of questions about safety and effectiveness as the devices cleared in premarket notification K973405. The new technological characteristics have not diminished safety or effectiveness. The submitted devices are substantially equivalent to existing 510(k) devices sold by Richard Wolf.

5.0 Performance Data

No known FDA performance standard exist.
The conformity assessment to relevant provisions of European Device Directive 93/42/EEC are pending.

6.0 Clinical Tests

No clinical tests performed.

7.0 Conclusions Drawn

These devices are designed and tested to guarantee the safety and effectiveness when used according to the instruction manual.

By: Robert L. Casarsa **Date:** Jan 5, 2000

Robert L. Casarsa
Quality Assurance Manager

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 3 0 2000

Mr. Robert L. Casarsa
Quality Assurance Manager
Richard Wolf Medical Instruments Corporation
353 Corporate Woods Parkway
Vernon Hills, Illinois 60061

Re: K000046
Trade Name: Knight Endoscopic Spine System
Regulatory Class: II
Product Code: HRX
Dated: January 5, 2000
Received: January 7, 2000

Dear Mr. Casarsa:

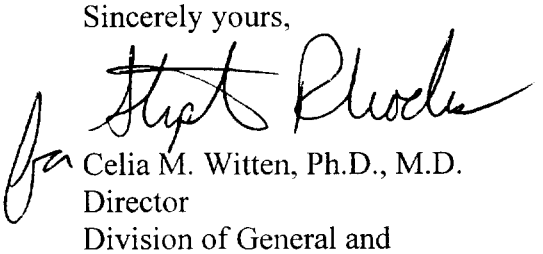
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

[redacted]

510(k) Number (if known): K000046

Device Name: **Knight Endoscopic Spinal Surgery System (KESS)**

Intended Use:

The "KESS" instrument set is used to perform endoscopic interventions in the lumbar spine, e.g. decompression of intervertebral discs. The intervention is performed through surgically produced passages.

The PANOVIEW PLUS **discoscope** is inserted through the accompanying **working sleeve.** It facilitates the visualization of the working instruments and the operating area. Irrigation and suction transport is effected through the stopcocks on the discoscope or through the irrigation attachments.

The **spinal cannula set** is used for local anesthesia and primary definition of the port of access. Single use and reusable cannulas are available.

The **dilator** serves as a guide for the working sleeve. It is introduced through the **obturator.**

The **x-ray jig** is a positioning aid to ensure accurate placement of the passage/port.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH Office of Device Evaluation (ODE)

Prescription Use X OR Over-The Counter

Per 21 CFR 801.109

The **insertion set** creates a first passage.

The **working sleeve / irrigation attachment / stop cock attachment** equips the port / channel to utilize the instrument set and to enable irrigation and suction through the stop cocks or irrigation attachments.

The **trephine** creates a window in the fibrous ring of the intervertebral disc.

Elevator / exploring hook / exploring probe / annulotome / dissector: These auxiliary instruments, inserted through the instrument channel of the discoscope, palpate, prepare, and remove tissue from the intervertebral disc.

The **forceps, rongeur, punch, scissors** and **deflector** grasp, sever, manipulate, and remove pathological tissue. Depending on the model, insertion is either through the instrument channel of the discoscope or directly through the working sleeve.

The **abrader / resector / burr** remove pathologic tissue. They are driven by an external motor; 2) suction is simultaneous with the cutting action of the motor.

The **instrument holding forceps** is used for holding the PANOVIEW PLUS Discoscope during an intra-operative x-ray.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH Office of Device Evaluation (ODE)

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Per 21 CFR 801.109

Indications and Field of Application:

For diagnosis and / or therapy in connection with endoscopic accessories in spinal surgery (arthroscopic micro discectomy (AMD), spinal endoscopy performed by qualified and trained medical personnel.

Contraindications:

Contraindications directly related to the product are currently unknown. Based on the patient's general condition, the attending physician must determine if the application is appropriate. For further information refer to the latest medical literature.

Combinations:

The KESS Instrument System is used in connection with endoscopic devices and endoscopic accessories.

CAUTION! Ensure devices used in combination are compatible n their intended use and relevant specifications, e.g., working length, diameter, etc. Comply with the device instruction manuals used in combination with the submitted devices.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K 000046

Prescription Use N
Per 21 CFR 801.109

OR

Over-The Counter_____